Minutes - Enpr-EMA Coordinating Group & networks meeting

Date: 11 June 2025; 15:30-17:00 CEST; online

Chairpersons: Pirkko Lepola / Gunter Egger

Invitees: Coordinating Group, Network members and observers (and speakers as applicable)

Agenda

Closed part: Coordinating group only

Possibilities for collaboration of ACT EU & Enpr-EMA

Laura Pioppo, ACT EU Programme Manager at the EMA, provided an overview of ACT EU, an initiative to support the implementation of the Clinical Trials Regulation, aiming to create a more favourable environment for clinical trials in the EU. Laura introduced the ACT EU work plan for 2025 and 2026 as well as the initiative's priority actions.

Several upcoming workshops were mentioned, including one on Bayesian statistics, an assessor's workshop on clinical trials in the paediatric population, and other workshops on external controls and platform trials.

The possibility of organising a joint ACT EU/Enpr-EMA workshop on paediatric clinical trials in early 2026 was discussed. The suggestion of establishing a programme committee to define the content of the agenda together was well received. A few potential topics brought up during the discussion included challenges faced by non-commercial trial sponsors, innovative trial designs (e.g. platform trials), and for example, the use of extrapolation.

Presentation: Possibility of an ACT EU – Enpr-EMA workshop

Strategic aims of Coordinating Group for 2025-2027

The group discussed potential strategic aims for Enpr-EMA, which had been circulated ahead of the meeting:

1. Preparing for upcoming EU medicine legislation and Enpr-EMA's expanded role (new Regulation Art. 95)
2. Reviewing of Enpr-EMA governance documents
3. Responding to/engaging with/influencing upcoming European initiatives and regulatory guidance documents

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4. Strengthening international collaboration
5. Developing new types of Enpr-EMA activities
6. Increasing Enpr-EMA's visibility

The group acknowledged the need to select only a few strategic priorities based on feedback from stakeholders and on feasibility considerations. The role of Enpr-EMA providing requested scientific information to support PDCO decisions was mentioned by a PDCO representative. Moreover, it was stated that regarding the inclusion of certain topics highlighted by the group (such as medical devices) feedback was also required from EMA management. The discussion ended with the expectation that a decision on the main strategic priorities would be taken at the Enpr-EMA meeting in the autumn.

Presentation: Strategic Aims of Enpr-EMA 2025-2027

Open part: Coordinating group, networks, working group chairpersons

Working group (WG) updates:

Paediatric clinical trial site quality criteria:

Ricardo Fernandes and Pernille Skovby provided an update on the group's work, mentioning the collection of feedback from networks and the impact of the update of the R3 Good Clinical Practice (GCP) guideline, which slightly slowed down the finalisation of the document, but is needed to be added on the definitions related to trial sites. When all comments received from networks have been implemented in the group's recommendation paper, a short public consultation is planned before its publication on Enpr-EMA's website. In addition, a scientific journal article is being prepared for publication.

Cross-border clinical trials:

Begonya Nafria highlighted the data collection from clinical trial sites, parents, and sponsors, and the analysis of global study protocols from clinicaltrials.gov for identifying potential discrimination of trial participation based on mother tongue and country of residence. Moreover, it was mentioned that data analyses of EU data from EudraCT and CTIS were underway. Solange Corriol-Rohou shared information about the EU-X-CT Multi-stakeholder Initiative of EFGCP and EFPIA on cross-border access to trials, emphasizing the importance of linking with the work done by Begonya's group. It was also noted that academic research groups meet real challenges to provide cross-border access due to smaller budgets, limiting the cost structure and remuneration payments for participants.

Patient and Public Involvement (PPI) and Young Person's Advisory Groups (YPAG):

Segolene Gaillard provided an update on the group, discussing the mapping of PPI capabilities across Europe and the preparation of a survey to be disseminated in the summer or early autumn 2025, including also the UK.

Paediatric research nurses:

Pamela Dicks provided an update, mentioning the surveys conducted and the need to analyse the data and write a report.

Clinical trials in emergency settings:

Pamela Dicks said that although this topic was rated highly relevant at the annual Enpr-EMA

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meeting in 2024, it was not clear what objectives a group on clinical trials in emergency settings should work towards. It was suggested to conduct a survey among Coordinating Group and Enpr-EMA members regarding the interest, need and potential aims for this group.
Update regarding annual meeting on 19/20 November 2025: The group reviewed the preliminary agendas for the annual meeting, which includes regulatory updates, updates on Enpr-EMA's activities, as well as sessions on innovative trial designs, and data use in paediatric research.